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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER PEFFLEY, MICHAEL F	
			ART UNIT 3730	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,163

Applicant(s)

JUN, MYONG-KI

Examiner

Michael Peffley

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-27, 29-31, 33 and 34 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's amendments and remarks, filed August 25, 2008, have been fully considered by the examiner now of record. The following is a complete response to the August 25, 2008 communication.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22, 26, 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. (US 6,514,251 B1) in view of the teaching of Pomeranz (6,032,077).

Regarding claims 21, 22, and 29, Ni et al. disclose an electrode for an electro-surgical operation device, comprising: a hollow electrode (49, Fig. 6) formed in a hollow tube shape extending from a closed tip (Fig. 6); a first non-insulation area formed to a predetermined length from the closed tip (col. 3, lines 44-46); a first insulation area formed on an outside surface of the hollow electrode beginning a predetermined length from the closed tip (as implied in col. 3, lines 44-46); a refrigerant tube (defined as 28 in Figs. 3 and 4), having a smaller diameter than a diameter of the hollow electrode, inserted into the hollow electrode (Fig. 6), the refrigerant tube configured to circulate pressurized (infusion pump, col. 4, lines 49-58) refrigerants so as to supply refrigerants (i.e. 0.9% saturated saline solution, col. 3, lines 16-21) from outside of a living body into the hollow electrode to cool living tissue in contact with at least one of the closed tip and

the hollow electrode, and to discharge the heat-exchanged refrigerants (Fig. 8) out of the living body (Fig. 7), the pressurized refrigerants being a pressurized saline solution (infusion pump connected to a hypertonic solution, col. 4, lines 53-55); at least one first hole (or refrigerant discharging mechanism) formed on an outside surface of the first non-insulation area (shown near the tip in Fig. 6); the at least one first hole operable to externally discharge a portion of the circulated pressurized refrigerants into the living tissue in contact with at least one of the closed tip and the hollow electrode (as shown by the arrows running through the holes). Ni et al. further disclose the device further comprising: a saline solution pipe (33, Fig. 3; and 38, Fig. 4) sheathing around the outside surface of the hollow electrode with a predetermined gap (33), and having a second non-insulation area at another predetermined length toward the closed tip (any non-insulation area on the electrode that has not been defined as the first non-insulation area) and a second insulation area on an outside surface of the saline solution pipe except the second non-insulation area (any insulation area not defined as the first insulation area); the saline solution pipe operable to infuse a saline solution having a relatively low pressure through the gap (infusion pump, col. 4, lines 53-55), and discharge the saline solution through at least one second hole (35) formed on an outside surface of the second non-insulation area (col. 4, lines 2-7). Ni et al. do not disclose flow control mechanism formed on the outside surface of the first non-insulation area.

Pomeranz discloses an analogous RF electrode device comprising a catheter having a hollow, tubular electrode (422 – Figure 19) and a refrigerant tube (404) for

supplying a pressurized coolant to the electrode. Pomeranz specifically disclose providing the electrode with a plurality of holes (430) for discharging fluid to tissue. A discharge mechanism in the form of a foam covering (432) serves to provide resistance to the flowing coolant and control the flow of the refrigerant from the holes (430) formed in the electrode tip.

To have provided the Ni et al device with a foam coating over the holes provided in the electrode assembly to control the flow of fluid from the electrode holes would have been an obvious design modification for one of ordinary skill in the art since Pomeranz fairly teaches that it is known to provide such a "discharge resistance" member in an analogous electrode device that delivers pressurized coolant to the electrode.

Regarding claims 26 and 27, the claimed method is anticipated by the normal use of the device as disclosed by Ni et al. in view of Pomeranz.

Regarding claim 30, Ni et al. in view of Pomeranz disclose the electrode of claim 21, wherein the closed tip of the hollow electrode (shown as 29 in Fig. 3 of Ni et al.) is a conductive spearhead (the closed tapered tip of Ni et al. is interpreted as a spearhead), and the hollow electrode and the spearhead are incorporated with each other (Figs. 3-7).

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. in view of Pomeranz as applied to claims 21 and 22 above and further in view of Hovda et al. (US 2003/0208194 A1).

Regarding claims 23 and 24, Ni et al. in view of Pomeranz disclose the electrode of claim 22, with the features described above, wherein the hollow electrode and the saline solution pipe are conductive (Ni et al., col. 3, lines 44-46), further comprising a power source (65, Fig. 8) for providing RF electricity (col. 4, lines 56-58) and which is capable of being configured to apply different power to the hollow electrode and the saline solution pipe in the form of a bipolar configuration; but does not disclose an insulation member formed on the surface of the hollow electrode to prevent short circuiting. Hovda et al. teach an electrosurgical device comprising an electrode (104, Fig. 12A), and a second conducting member (112) which forms an annular gap (54) which defines a fluid path (83) for a conducting liquid (50, para. [0103]); an insulation member formed on the surface of the electrode (78) which would prevent short circuit of the saline solution supplied through the gap between the electrode and the saline solution pipe; and an insulation packing (102) provided between the electrode and the saline solution pipe (Fig. 12A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention as disclosed by Ni et al. in view of Pomeranz by including the saline solution pipe and insulation member as taught by Hovda et al. in order to ablate desired tissue in a bipolar configuration and to provide a pathway for electrical current flow between the active and return electrodes.

Claims 25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. in view of Pomeranz as applied to claims 21 and 29 above, and further in view of Brucker et al. (6,017,338).

Regarding claims 25 and 33, Ni et al. in view of Pomeranz disclose the electrode of claims 21 and 29, but do not disclose the flow control mechanism as a porous metal sintered body layer. Brucker et al. teach an ablation catheter (22) with a central lumen (28) for introducing fluids into the catheter. The tip of the catheter (26) is made of sintered metal which contains a plurality of randomly formed through-passages and which permits a controlled flow of fluid from the catheter (col. 5, lines 30-34) and acts as a discharge resistance mechanism. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Ni et al. in view of Pomeranz by forming the flow control mechanism of porous sintered metal in order to obtain a desired discharged fluid profile in the tissue.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. (US 6,514,251 B1) in view of the teaching of Pomeranz (6,032,077) and further in view of the teaching of Schwartz et al (6,969,373).

Regarding claim 31, Ni et al. in view of Pomeranz has been addressed previously, and this combination fails to disclose the particular flow control mechanism including an aligning tube disposed over the hollow tube. Schwartz et al. disclose the electrode of claim 29, wherein the flow control mechanism is a hollow tube sheathing around the outside surface of the first non-insulation area (Schwartz et al., Fig. 11), and having a third hole on the outside surface (Schwartz et al., element 84, Fig. 11) of the

hollow tube, the flow control mechanism controlling a volume of the discharged pressurized refrigerants by alternately aligning the at least one first hole of the hollow electrode and the third hole of the hollow tube and operating as a discharge resistance to the pressurized refrigerants discharged from the at least one first hole (Schwartz et al., col. 17, lines 11-14; and Fig. 11).

To have provided the Ni et al device, as modified by the teaching of Pomeranz, with a hollow tube sheathing including means for aligning the holes of the sheath with the holes on the electrode to control the flow of refrigerant would have been an obvious design modification for one of ordinary skill in the art given the teaching of Schwartz et al.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. in view of Pomeranz as applied to claim 21 above, and further in view of Milder (5,281,215).

Regarding claim 34, Ni et al. in view of Schwartz et al. disclose the electrode of claim 21, but do not disclose the pressurized refrigerants having a pressure of approximately 700 to 1060 kPa. Milder teaches a cooling liquid under pressure, such as a chlorinated fluorocarbon at 150 pounds per square inch (col. 6, lines 35-46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Ni et al. in view of Pomeranz by using a pressurized refrigerant as taught by Milder in order to cool the tip (col. 6, lines 65-66).

Allowable Subject Matter

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

The examiner now of record has applied a new piece of prior art to address the newly added limitations.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Imran et al (5,348,554) discloses another device having a hollow electrode having holes therein for controlled delivery of a pressurized coolant.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
February 23, 2009

